SUPPLEMENTAL INFORMATION

June 28, 2004

NOTE: The following language has been extracted verbatim from the currently applicable NELAC Standard, as operational language that will be governed by NELAC Policies, Procedures, and Standard Operating Procedures (SOPs). For purposes of initial separation, however, this document is representative of the language exactly as it appeared in the NELAC Standard prior to being removed.

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1.4.7 The Accrediting Authority Review Board

a) The non-voting member shall be a representative of the USEPA and appointed by the NELAP Director. The appointment should be rotated among the EPA Regions and EPA Headquarters.

b) The five voting members shall consist of one federal accrediting authority official and four state accrediting authority officials, of which at least three must be from NELAP-recognized state accrediting authorities.

    1) The state accrediting authority officials should be from different EPA Regions.

    2) The appointments must be made in such a manner that the correct mix of membership is maintained at all times. Any AARB member appointed prior to July 1, 1999 will remain an AARB member even though the correct mix of membership may not be attained until July 1, 2004.

c) Appointments to the AARB are made by the NELAP Director after consultation with the NELAC Board of Directors. The Director will solicit nominees from the NELAC stakeholders and present them to the Board of Directors. Nominations are to be submitted to the NELAP Director at least three months prior to the NELAC annual meeting.

d) Voting members of the AARB shall not be NELAP staff, on the NELAC Board of Directors or a member of a NELAC committee. The AARB annually selects one of its members to serve as its chair.

1.5 CONDUCT OF CONFERENCE BUSINESS

1.5.1 Acceptable Standards Development Organizations

NELAC will consider for adoption standards submitted by any Standards Development Organization, provided it meets the minimum requirements of Openness; Balance of Interest; Due Process; an Appeals Process; and a Defined Consensus Process. An organization that qualifies under these criteria shall be designated an Acceptable Standards Development Organization (ASDO). Specific requirements are as follows.

a. Openness. The process of developing standards shall be designed to be open, ensuring that standards are readily available, allowing any interested parties to review the proposed standards, and submit comments on those standards for consideration by the committee that develops the standard.

b. Balance of Interest. The organization shall have a process that defines how various segments (e.g. private vs. public or manufacturer vs. user) are distributed on committees to ensure a representative mixture of members so that a variety of interests are included.

c. Due Process. The organization shall have a written policy that describes how a standard is adopted and the process for ensuring that a variety of opinions are considered in developing the standard; e.g., a ballot process that identifies the procedure for revising a standard and the basis for submitting and/or handling a negative vote on the standard would meet these criteria.

d. Appeals Process. The organization shall have a written policy that identifies how a participant can dispute the decision of the committee on a standard and the process for responding to that dispute.

e. Defined Consensus Process. The organization shall have a defined consensus process that ensures general agreement, but not necessarily unanimity. It shall include a process for attempting to resolve objections by interested parties, including informing the objector of the disposition of his or her objection(s) and the reasons why, and a provision allowing committee members to change their votes after reviewing the objections.

1.5.2 Standards Review

Standards review is the responsibility of the Standards Review Committee (SRC), whose main function is the interface between Acceptable Standards Development Organizations (ASDO) and the NELAC Membership. Duties are as

follows:

a. review all standards received by NELAC from ASDOs for consistency with governmental, regulatory, and NELAC requirements; and incorporating, to the extent applicable, ISO/IEC 17025, ISO/IEC Guide 43, and ISO/IEC 58.

b. prepare an assessment of the advantages and disadvantages of each standard;

c. work with ASDOs, to both solicit standards and to resolve any issues identified after consideration of proposed standards;

d. prepare and publish a report, with recommendations for disposition, on proposed standards received by the SRC;

e. present proposed standards with recommendations for NELAC voting; and

f. perform regulatory coordination functions, including provision of current information on pertinent laws and regulations, and developing model legislation and regulation for use by Accrediting Authorities.

1.5.2.1 Solicitation of Proposed Standards

The SRC will accept proposed standards from any ASDO. These standards may be solicited or unsolicited. Solicited standards will result from the SRC receiving recommendations on the need for new or modified standards from its own membership, the NELAP Recognized Accrediting Authorities, the NELAC Board of Directors, or NELAC Stakeholders.

The SRC will solicit standards, in the form of a Request for Standard (RFS) that will include the following: the need for a standard; a general description and essential elements of the standard; and the expected due date of the standard.

As the need arises, a RFS will be made available to ASDOs, requesting a statement of intent within thirty days from any interested ASDO. Within a further thirty days, the SRC will make available the names of the ASDOs that have indicated their intent to submit a proposed standard. The SRC may not preclude any ASDO from submitting a proposed standard in response to a RFS, or from submitting any unsolicited standard.

1.5.2.2 Consideration of Proposed Standards

Any standard to be presented for vote at an Annual Meeting of NELAC must first be discussed by the membership at the immediately preceding NELAC Interim Meeting. The SRC will hold an open working session at the NELAC Interim Meeting to consider all the solicited and unsolicited proposed standards that

have been submitted at least 90 days preceding that meeting. The SRC may, at its discretion, accept proposed standards after the 90 day deadline if the SRC has determined that expedited adoption of the standard will be necessary. Pursuant to that Interim Meeting, and no later than 30 days after that meeting, it will notify the ASDO of its recommendations. These recommendations will be either:

1. the standard will be recommended for NELAC approval without further modification;

2. the standard will be recommended for NELAC approval subject to minor changes being made by the ASDO; or

3. the standard is considered unsuitable and will not be recommended for approval if brought to the vote.

If the standard as submitted is not to be recommended, the SRC will work with the ASDO to reach mutual agreement on appropriate modifications. Proposed standards considered by the SRC to require major changes or otherwise unsuitable and not recommended by the SRC may be withdrawn by the ASDO from consideration and presentation for vote at the Annual Meeting. However, the ASDO will retain the right to have the standard brought to vote at the Annual Meeting.

The SRC will prepare a written assessment of each proposed standard that has been discussed at the preceding Interim Meeting. The SRC will make available or reference (where the standard is generally available to the public) all proposed standards, together with its written assessment, at least 30 days prior to the Annual Meeting.

1.5.2.3 Voting for the Approval of Proposed Standards

The Chair of the SRC, or his/her designee will present proposed standards received from the ASDOs for vote at the NELAC Annual Meeting. Included in that presentation will be a summary of the SRC's recommendations, with reasons. The options available to NELAC will be to adopt or reject the standard as submitted. No standard may be modified by NELAC. However, a floor amendment may be made, subject to Article VII, Section 4 of the NELAC Bylaws, to adopt a standard under conditions as defined in an administrative policy.

1.5.2.4 Disposition of Standards Not Adopted

a.If, during the voting session at the Annual NELAC Meeting, NELAC does not adopt a proposed standard, the SRC will prepare a report of the reasons to the extent that they are readily apparent and return it to the ASDO within 30 days of that Annual Meeting.

APPENDIX A - GLOSSARY

Acceptance Criteria: specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC)

Accreditation: the process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is a voluntary one. (NELAC)

Accrediting Authority: the Territorial, State, or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation (NELAC)[1.4.2.3]

Accrediting Authority Review Board (AARB): five voting members from Federal and State Accrediting Authorities and one non-voting member from USEPA, appointed by the NELAP Director, in consultation with the NELAC Board of Directors, for the purposes stated in 1.4.7.e. (NELAC) [1.4.7]

Accuracy: the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (QAMS)

Assessor Body: the organization that actually executes the accreditation process, i.e., receives and reviews accreditation applications, reviews QA documents, reviews proficiency testing results, performs on-site assessments, etc., whether EPA, the State, or contracted private party. (NELAC)

Analyst: the designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality. (NELAC)

Applicant Laboratory or **Applicant:** the laboratory or organization applying for NELAP accreditation. (NELAC)

Assessment: the evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of NELAC). (NELAC)

Assessment Criteria: the measures established by NELAC and applied in establishing the extent to which an applicant is in conformance with NELAC requirements. (NELAC)

Assessment Team: the group of people authorized to perform the on-site inspection and proficiency testing data evaluation required to establish whether an applicant meets the criteria for NELAP accreditation. (NELAC)

Assessor: one who performs on-site assessments of accrediting authorities and laboratories' capability and capacity for meeting NELAC requirements by examining the records and other physical evidence for each one of the tests for which accreditation has been requested. (NELAC)

Audit: a systematic evaluation to determine the conformance to quantitative *and qualitative* specifications of some operational function or activity. (EPA-QAD)

Batch: environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one to 20 environmental samples of the same NELAC-defined matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An **analytical batch** is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples. (NELAC Quality Systems Committee)

Blank: a sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. Blanks include:

> Equipment Blank: a sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (NELAC)
>
> Field Blank: blank prepared in the field by filling a clean container with pure de-ionized water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER)
>
> Instrument Blank: a clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)

Method Blank: a sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses. (NELAC)

Reagent Blank: (method reagent blank): a sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps. (QAMS)

Blind Sample: a sub-sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process. (NELAC)

Calibration: set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards. (VIM: 6.11)

1) In calibration of support equipment the values realized by standards are established through the use of Reference Standards that are traceable to the International System of Units (SI).

2) In calibration according to test methods, the values realized by standards are typically established through the use of Reference Materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications.

Calibration Curve: the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (NELAC)

Calibration Method: a defined technical procedure for performing a calibration. (NELAC)

Calibration Standard: a substance or reference material used to calibrate an instrument. (QAMS)

Certified Reference Material (CRM): a reference material one or more of whose property values are certified by a technically valid procedure,

accompanied by or traceable to a certificate or other documentation which is issued by a certifying body. (ISO Guide 30 - 2.2)

Chain of Custody Form: record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; collector; time of collection; preservation; and requested analyses. (NELAC)

Clean Air Act: the enabling legislation in 42 U.S.C. 7401 *et seq.*, Public Law 91-604, 84 Stat. 1676 Pub. L. 95-95, 91 Stat., 685 and Pub. L. 95-190, 91 Stat., 1399, as amended, empowering EPA to promulgate air quality standards, monitor and to enforce them. (NELAC)

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA/Superfund): the enabling legislation in 42 U.S.C. 9601-9675 *et seq*., as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), 42 U.S.C. 9601*et seq.*, to eliminate the health and environmental threats posed by hazardous waste sites. (NELAC)

Confidential Business Information (CBI): information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation or products. NELAC and its representatives agree to safeguarding identified CBI and to maintain all information identified as such in full confidentiality.

Confirmation: verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to:

Second column confirmation
Alternate wavelength
Derivatization
Mass spectral interpretation
Alternative detectors or
Additional cleanup procedures.
(NELAC)

Conformance: an affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. (ANSI/ASQC E4-1994)

Contributor: a participant in NELAC who is not a Voting Member. Contributors include representatives of laboratories, manufacturers, industry, business, consumers, academia, laboratory associations, laboratory accreditation associations, counties, municipalities, and other political subdivisions, other

federal and state officials not engaged in environmental activities, and other persons who are interested in the objectives and activities of NELAC.

Corrective Action: the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence. (ISO 8402)

Critical Finding: a finding or a combination of findings that results in a significant negative effect on data quality or defensibility, if not corrected. (NELAC)

Data Audit: a qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality (i.e., that they meet specified acceptance criteria). (NELAC)

Data Reduction: the process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useable form. (EPA-QAD)

Deficiency: See Finding and Critical Finding

Delegate: any environmental official of the States or the Federal government not sitting in the House of Representatives, who is eligible to vote in the House of Delegates. (NELAC)

Demonstration of Capability: a procedure to establish the ability of the analyst to generate acceptable accuracy. (NELAC)

Denial: to refuse to accredit in total or in part a laboratory applying for initial accreditation or resubmission of initial application. (NELAC)[4.4.1]

Detection Limit: the lowest concentration or amount of the target analyte that can be identified, measured, and reported with confidence that the analyte concentration is not a false positive value. See Method Detection Limit. (NELAC)

Document Control: the act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed. (ASQC)

Environmental Laboratory Advisory Board (ELAB): a Federal Advisory Committee, with members appointed by EPA and composed of a balance of non-state, non-federal representatives, from the environmental laboratory community, and chaired by an ELAB member. (NELAC)

Environmental Monitoring Management Council (EMMC): an EPA Committee consisting of EPA managers and scientists, organized into a Policy Council, a Steering Group, *ad hoc* Panels, and work groups addressing specific objectives, established to address EPA-wide monitoring issues. (NELAC)

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA): the enabling legislation under 7 U.S.C. 135 *et seq.,* as amended, that empowers the EPA to register insecticides, fungicides, and rodenticides. (NELAC)

Federal Water Pollution Control Act (Clean Water Act, CWA): the enabling legislation under 33 U.S.C. 1251 *et seq.*, Public Law 92-50086 Stat. 816, that empowers EPA to set discharge limitations, write discharge permits, monitor, and bring enforcement action for non-compliance. (NELAC)

(Effective July 1, 2003)

Field Measurement: The determination of physical, biological, or radiological properties, or chemical constituents; that are measured on-site, close in time and space to the matrices being sampled/measured, following accepted test methods. This testing is performed in the field outside of a fixed-laboratory or outside of an enclosed structure that meets the requirements of a mobile laboratory.

Field of Accreditation: (previously Field of Testing) NELAC's approach to accrediting laboratories by matrix, technology/method and analyte/analyte group. Laboratories requesting accreditation for a matrix-technology/method-analyte/analyte group combination or for an updated/improved method are required to submit only that portion of the accreditation process not previously addressed. (NELAC)

Field of Proficiency Testing: NELAC's approach to offering proficiency testing by matrix, technology, and analyte/analyte group.

Finding: an assessment conclusion, referenced to a NELAC Standard and supported by objective evidence that identifies a deviation from a NELAC requirement. **See Critical Finding.**

Governmental Laboratory: as used in these standards, a laboratory owned by a Federal, state, or tribal government; includes government-owned contractor-operated laboratories. (NELAC).

Holding Times (Maximum Allowable Holding Times): the maximum times that samples may be held prior to analysis and still be considered valid or not compromised. (40 CFR Part 136)

Inspection: an activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformance is achieved for each characteristic. (ANSI/ASQC E4-1994)

Interim Accreditation: temporary accreditation status for a laboratory that has met all accreditation criteria except for a pending on-site assessment which has been delayed for reasons beyond the control of the laboratory. (NELAC)

Internal Standard: a known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method. (NELAC)

International System of Units (SI): the coherent system of units adopted and recommended by the General Conference on Weights and Measures. (CCGPM) (VIM 1.12)

Laboratory: a body that calibrates and/or tests. (ISO 25)

Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample): a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (NELAC)

Laboratory Duplicate: aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently. (NELAC)

Legal Chain of Custody Protocols: procedures employed to record the possession of samples from the time of sampling until analysis and are performed at the special request of the client. These protocols include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples by the laboratory. **In addition, these protocols document all handling of the samples within the laboratory**. (NELAC)

Limit of Detection (LOD): an estimate of the minimum amount of a substance that an analytical process can reliably detect. An LOD is analyte-and matrix-specific and may be laboratory-dependent.

Limits of Quantitation (LOQ): The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

Manager (however named): the individual designated as being responsible for the overall operation, all personnel, and the physical plant of the environmental laboratory. A supervisor may report to the manager. In some cases, the supervisor and the manager may be the same individual. (NELAC)

Matrix: the substrate of a test sample.

Field of Accreditation Matrix: these matrix definitions shall be used when accrediting a laboratory (see Field of Accreditation).

Drinking Water: any aqueous sample that has been designated a potable or potential potable water source.

Non-Potable Water: any aqueous sample excluded from the definition of Drinking Water matrix. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.

Solid and Chemical Materials: includes soils, sediments, sludges, products and by-products of an industrial process that results in a matrix not previously defined.

Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Air and Emissions: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device. (NELAC)

Quality System Matrix: These matrix definitions are an expansion of the field of accreditation matrices and shall be used for purposes of batch and quality control requirements (see Appendix D of Chapter 5). These matrix distinctions shall be used:

Aqueous: any aqueous sample excluded from the definition of Drinking Water matrix or Saline/Estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.

Drinking Water: any aqueous sample that has been designated a potable or potential potable water source.

Saline/Estuarine: any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

Non-aqueous Liquid: any organic liquid with <15% settleable solids.

Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Solids: includes soils, sediments, sludges and other matrices with >15% settleable solids.

Chemical Waste: a product or by-product of an industrial process that results in a matrix not previously defined.

Air and Emissions: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device. (NELAC)

Matrix Spike (spiked sample or fortified sample): a sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of Target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency. (QAMS)

Matrix Spike Duplicate (spiked sample or fortified sample duplicate): a second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte. (QAMS)

May: denotes permitted action, but not required action. (NELAC)

Measurement Quality Objectives (MQOs): the desired sensitivity, range, precision, and bias of a measurement.

Measurement System: a test method, as implemented at a particular laboratory, and which includes the equipment used to perform the test and the operator(s).

Method: 1. see Test Method. 2. Logical sequence of operations, described generically, used in the performance of measurements. (VIM 2.4)

Method Detection Limit: one way to establish a Limit of Detection, defined as the minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte.

Mobile Laboratory: A portable enclosed structure with necessary and appropriate accommodation and environmental conditions as described in

Chapter 5, within which testing is performed by analysts. Examples include but are not limited to trailers, vans, and skid-mounted structures configured to house testing equipment and personnel.

Must: denotes a requirement that must be met. (Random House College Dictionary)

National Accreditation Database: the publicly accessible database listing the accreditation status of all laboratories participating in NELAP. (NELAC)

National Institute of Standards and Technology (NIST): an agency of the US Department of Commerce's Technology Administration that is working with EPA, States, NELAC, and other public and commercial entities to establish a system under which private sector companies and interested States can be accredited by NIST to provide NIST-traceable proficiency testing (PT) to those laboratories testing drinking water and wastewater. (NIST)

National Environmental Laboratory Accreditation Conference (NELAC): a voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP. (NELAC)

National Environmental Laboratory Accreditation Program (NELAP): the overall National Environmental Laboratory Accreditation Program of which NELAC is a part. (NELAC)

National Voluntary Laboratory Accreditation Program (NVLAP): a program administered by NIST that is used by providers of proficiency testing to gain accreditation for all compounds/matrices for which NVLAP accreditation is available, and for which the provider intends to provide NELAP PT samples. (NELAC)

Negative Control: measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results. (NELAC)

NELAC Standards: the plan of procedures for consistently evaluating and documenting the ability of laboratories performing environmental measurements to meet nationally defined standards established by the National Environmental Laboratory Accreditation Conference. (NELAC)

NELAP Recognition: the determination by the NELAP Director that an accrediting authority meets the requirements of the NELAP and is authorized to grant NELAP accreditation to laboratories. (NELAC)

Non-governmental Laboratory: any laboratory not meeting the definition of the governmental laboratory. (NELAC)

Performance Audit: the routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory. (NELAC)

Positive Control: measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from positive test subjects. (NELAC)

Precision: the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms. (NELAC)

Preservation: refrigeration and/or reagents added at the time of sample collection (or later) to maintain the chemical and/or biological integrity of the sample. (NELAC)

Primary Accrediting Authority: the agency or department designated at the Territory, State or Federal level as the recognized authority with responsibility and accountability for granting NELAC accreditation for a specified field of testing. (NELAC)

Procedure: Specified way to carry out an activity or a process. Procedures can be documented or not. (ISO 9000: 2000 and Note1)

Proficiency Testing: a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (NELAC)[2.1]

Proficiency Testing Oversight Body/Proficiency Testing Provider Accreditor (PTOB/PTPA): an organization with technical expertise, administrative capacity and financial resources sufficient to implement and operate a national program of PT provider evaluation and oversight that meets the responsibilities and requirements established by NELAC standards. (NELAC)

Proficiency Testing Program: the aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories. (NELAC)

Proficiency Testing Study Provider: any person, private party, or government entity that meets stringent criteria to produce and distribute NELAC PT samples, evaluate study results against published performance criteria and report the

results to the laboratories, primary accrediting authorities, PTOB/PTPA, and NELAP. (NELAC)

Proficiency Test Sample (PT): a sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria. (QAMS)

Protocol: a detailed written procedure for field and/or laboratory operation (e.g., sampling, analysis) which must be strictly followed. (EPA-QAD)

Quality Assurance: an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (QAMS)

Quality Assurance [Project] Plan (QAPP): a formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EPA-QAD)

Quality Control: the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. (QAMS)

Quality Control Sample: a sample used to assess the performance of all or a portion of the measurement system. QC samples may be Certified Reference Materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking.

Quality Manual: a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users. (NELAC)

Quality System: a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC. (ANSI/ASQC E-41994)

Raw Data: any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, including dictated

observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g., tapes which have been transcribed verbatim, data and verified accurate by signature), the exact copy or exact transcript may be submitted. (EPA-QAD)

Recognition: previously known as reciprocity. The mutual agreement of two or more parties (i.e., States) to accept each other's findings regarding the ability of environmental testing laboratories in meeting NELAC standards. (NELAC)

Reference Material: a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (ISO Guide 30-2.1)

Reference Standard: a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. (VIM-6.08)

Reference Toxicant: the toxicant used in performing toxicity tests to indicate the sensitivity of a test organism and to demonstrate the laboratory's ability to perform the test correctly and obtain consistent results (see Chapter 5, Appendix D, section 2.1f). (NELAC)

Replicate Analyses: the measurements of the variable of interest performed identically on two or more sub-samples of the same sample within a short time interval. (NELAC)

Requirement: denotes a mandatory specification; often designated by the term "shall". (NELAC)

Resource Conservation and Recovery Act (RCRA): the enabling legislation under 42 USC 321 *et seq.* (1976), that gives EPA the authority to control hazardous waste from the "cradle-to-grave", including its generation, transportation, treatment, storage, and disposal. (NELAC)

Revocation: the total or partial withdrawal of a laboratory's accreditation by the accrediting authority. (NELAC)[4.4.3]

Safe Drinking Water Act (SDWA): the enabling legislation, 42 USC 300f *et seq.* (1974), (Public Law 93-523), that requires the EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations. (NELAC)

Sample Tracking: procedures employed to record the possession of the samples from the time of sampling until analysis, reporting, and archiving. These procedures include the use of a Chain of Custody Form that documents the

collection, transport, and receipt of compliance samples to the laboratory. In addition, access to the laboratory is limited and controlled to protect the integrity of the samples. (NELAC)

Secondary Accrediting Authority: the Territorial, State or federal agency that grants NELAC accreditation to laboratories, based upon their accreditation by a NELAP-recognized Primary Accrediting Authority. See also **Recognition** and **Primary Accrediting Authority**. (NELAC)

Selectivity: (Analytical chemistry) the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances. (EPA-QAD)

Sensitivity: the capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. (NELAC)

Shall: denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled. (ANSI)

Should: denotes a guideline or recommendation whenever noncompliance with the specification is permissible. (ANSI)

Spike: a known mass of target analyte added to a blank sample or sub-sample; used to determine recovery efficiency or for other quality control purposes. (NELAC)

Standard: the document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of NELAC and meets the approval requirements of NELAC procedures and policies. (ASQC)

Standard Operating Procedures (SOPs): a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks. (QAMS)

Standard Method: a test method issued by an organization generally recognized as competent to do so.

Standardized Reference Material (SRM): a certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method. (EPA-QAD)

Statistical Minimum Significant Difference (SMSD): the minimum difference between the control and a test concentration that is statistically significant; a measure of test sensitivity or power. The power of a test depends in part on the number of replicates per concentration, the significance level selected, e.g., 0.05, and the type of statistical analysis. If the variability remains constant, the sensitivity of the test increases as the number of replicates is increased. (NELAC)

Supervisor (however named): the individual(s) designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy and upkeep, quality assurance/quality control duties and ascertaining that technical employees have the required balance of education, training and experience to perform the required analyses. (NELAC)

Surrogate: a substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes. (QAMS)

Suspension: temporary removal of a laboratory's accreditation for a defined period of time, which shall not exceed six months, to allow the laboratory time to correct deficiencies or area of non-compliance with the NELAC standards. (NELAC)[4.4.2]

Technical Director: individual(s) who has overall responsibility for the technical operation of the environmental testing laboratory. (NELAC)

Technology: a specific arrangement of analytical instruments, detection systems, and/or preparation techniques.

Test: a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate. (ISO/IEC Guide 2-12.1, amended)

Test Method: an adoption of a scientific technique for performing a specific measurement, as documented in a laboratory SOP or as published by a recognized authority.

Testing Laboratory: a laboratory that performs tests. (ISO/IEC Guide 2-12.4)

Test Sensitivity/Power: the minimum significant difference (MSD) between the control and test concentration that is statistically significant. It is dependent on the number of replicates per concentration, the selected significance level, and

the type of statistical analysis (see Chapter 5, Appendix D, section 2.4.a). (NELAC)

Tolerance Chart: A chart in which the plotted quality control data is assessed via a tolerance level (e.g. +/- 10% of a mean) based on the precision level judged acceptable to meet overall quality/data use requirements instead of a statistical acceptance criteria (e.g. +/- 3 sigma) (applies to radiobioassay laboratories). (ANSI)

Toxic Substances Control Act (TSCA): the enabling legislation in 15 USC 2601 *et seq.*, (1976), that provides for testing, regulating, and screening all chemicals produced or imported into the United States for possible toxic effects prior to commercial manufacture. (NELAC)

Traceability: the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons. (VIM-6.12)

United States Environmental Protection Agency (EPA): the federal governmental agency with responsibility for protecting public health and safeguarding and improving the natural environment (i.e., the air, water, and land) upon which human life depends. (US-EPA)

Validation: the confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

Verification: confirmation by examination and provision of evidence that specified requirements have been met. (NELAC)

NOTE: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

The result of verification leads to a decision either to restore in service, to perform adjustment, to repair, to downgrade, or to declare obsolete. In all cases, it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record.

Voting Member: officials in the employ of the Government of the United States, and the States, the Territories, the Possessions of the United States, or the District of Columbia and who are actively engaged in environmental regulatory programs or accreditation of environmental laboratories. (NELAC)

Work Cell: a well-defined group of analysts that together perform the method analysis. The members of the group and their specific functions within the work cell must be fully documented. (NELAC)

Working Range: the difference between the Limit of Quantitation and the upper limit of measurement system calibration.

Sources:

40CFR Part 136

American Society for Quality Control (ASQC), Definitions of Environmental Quality Assurance Terms, 1996

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Appendix A – QUESTIONS OF UNIFORMITY PROCEDURE

A.1 PURPOSE

In the event where two or more parties cannot resolve an issue of interpretation of a standard, the following procedure shall be followed. This procedure may be initiated by any involved party and is to be used when the appeal procedure provided by the Accrediting Authority has been exhausted or is not appropriate.

A.2 PROCEDURE FOR INITIATION OF RESOLUTION BY AFFECTED PARTIES

A.2.1 Initial Decision/Interpretation Procedure

a) The affected party shall contact the involved Accrediting Authority(s) (AA)(s) in writing with a copy to the NELAP Director. The request shall include the reference for the affected standard and a statement of the variances in interpretation made by the AA(s) as well as a summary explaining the affected party's position.

b) The parties shall discuss the difference in interpretation within 7 days of notification of the issue.

c) If the affected parties reach an agreement on interpretation the NELAP Director is informed in writing of their decision.

d) If the affected parties cannot reach an agreement the request is forwarded in writing to the NELAP Director within 14 days by the affected party(s)

A.2.2 Decision/Interpretation Procedure When Affected Parties Cannot Reach an Agreement

a) Within 7 days after receiving the request from the affected parties, the NELAP Director shall forward the request to the author of the applicable standard *or* AA workgroup for an interpretation/decision.

b) The author of the applicable standard or AA workgroup shall have 45 days to inform the director of their interpretation/decision

c) The director shall inform the affected parties of the interpretation within 7 days.

d) The effective parties shall notify the director of accepting or appeal the interpretation/decision within 7 days of being informed of the interpretation/decision.

A.3 APPEAL PROCEDURE

If the affected parties disagree with the decision/interpretation, the issue is appealed in writing to the NELAP Board of Directors for final resolution by being placed on the agenda of the next scheduled meeting for review and a decision.

A.4 POSTING OF DECISION

Once the issue has been resolved, the NELAP Director shall post the question and resolution within 14 days on the NELAC web site.